MediWound Announces Positive Outcome of Interim Assessment for its EscharEx U.S. Phase 2 Adaptive Design Study

July 28, 2021

Independent Data Monitoring Committee Recommends Continuation of the Study with No Changes to Study Sample Size

No Safety Concerns Identified

Full Study Enrollment Expected by Year-End 2021; Data Readout Expected in the First Half of 2022

YAVNE, Israel, July 28, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced a positive outcome from a planned interim sample size re-estimation of its ongoing EscharEx® U.S. phase 2 adaptive design study for the treatment of venous leg ulcers (VLUs), designed to assess the safety and efficacy of EscharEx compared to gel vehicle (placebo control) and non-surgical standard-of-care (either enzymatic or autolytic debridement).

Based on the Independent Data Monitoring Committee's (IDMC) recommendation, no changes to the original enrollment target of 120 patients is required to maintain the pre-specified statistical power of 80 percent or greater on the study's primary endpoint of incidence of complete debridement compared with gel vehicle. In addition, the IDMC reviewed the data of all subjects treated and no safety concerns were identified in the study population. The IDMC's recommendations were based on the results of a pre-specified interim conditional power assessment conducted after approximately two-thirds of the originally targeted of 120 patients completed the debridement treatment.

"We are very pleased with the IDMC's recommendation to continue the EscharEx study as originally planned without modifying the study sample size," said Sharon Malka, Chief Executive Officer of MediWound. "This interim outcome suggests that EschareEx is safe and tolerable, and increases our confidence that EscharEx may prove to be an effective non-surgical therapy for debridement of chronic wounds. With a clear unmet medical need for a non-surgical rapid and effective debridement agent in the outpatient setting, EscharEx has the potential to improve on the current standard of care and have a meaningful impact on chronic wound management. We remain on track to complete patient enrollment by year-end, with data readout expected in the first half of 2022."

The multicenter, prospective, randomized, placebo-controlled, adaptive design study, evaluating the safety and efficacy of EscharEx in debridement of VLUs. The study is expected to enroll 120 patients at approximately 20 clinical sites, primarily in the U.S. Study participants are randomized to either EscharEx, placebo control or non-surgical standard-of-care of either enzymatic or autolytic debridement, at a ratio of 3:3:2, with a three-month follow-up. The study includes a pre-defined interim assessment for futility and potential sample size adjustment. The primary endpoint is incidence of complete debridement compared to gel vehicle placebo control. Secondary endpoints include time to achieve complete debridement, reduction of pain, reduction of wound area, granulation tissue and quality of life. Incidence and time to achieve wound closure will be assessed as safety measurements.

About EscharEx

EscharEx, our bioactive therapy for debridement of chronic and other hard-to-heal wounds, is a product candidate in advanced stages of clinical development. EscharEx, a concentrate of proteolytic enzymes enriched in bromelain, is an easy-to-use product candidate, for topical daily applications, which designed for the outpatient setting.

In two phase 2 trials, EscharEx was well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, with only few daily applications. The mechanism of action of EscharEx is mediated by the proteolytic enzymes that cleave and remove the necrotic tissue and prepare the wound bed for healing. EscharEx is an investigational product, currently under a U.S. phase 2 adaptive design study.

About MediWound Ltd.

MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, bio-therapeutic solutions for tissue repair and regeneration. Our strategy leverages our enzymatic technology platform, focused on next-generation bioactive therapies for burn care, wound care and tissue repair.

NexoBrid, our commercial orphan biological product for non-surgical eschar removal of deep-partial and full-thickness thermal burns, is a bromelain-based biological product containing a sterile mixture of proteolytic enzymes that selectively removes burn eschar within four hours without harming surrounding viable tissue. NexoBrid is currently marketed in the European Union and other international markets and is at registration-stage in the U.S. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx, our next-generation bioactive therapy for debridement of chronic and hard-to-heal wounds, is a product candidate in advanced stages of development. In two Phase 2 studies, EscharEx was well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, with only a few daily applications.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development.

Committed to innovation, we are dedicated to improving quality of care and patient lives. For more information, please visit www.mediwound.com.

Cautionary Note Regarding Forward-Looking Statements

MediWound caution you that all statements other than statements of historical fact included in this press MediWound caution you that all statements other than statements of historical fact included in this press release that address activities, events, or developments that we expect, believe, or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting us and are subject to risks, assumptions, uncertainties and factors, all of which are difficult to predict and many of which are beyond our control. Actual results may differ materially from those expressed or implied by the forward-looking statements in this press release. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "continues," "believe," "guidance," "outlook," "target," "future," "potential," "goals" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "could," "may," or similar expressions.

Specifically, this press release contains forward-looking statements concerning the anticipated progress, development, study design, objectives anticipated timelines, expectations and commercial potential of our products and product candidates, including EscharEx. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the uncertain, lengthy and expensive nature of the product development process; the timing and conduct of our studies of our products and product candidates, including the timing, progress and results of current and future clinical studies, and our research and development programs; our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products and products; our expectations regarding future growth, including our ability to develop new products; risks related to our contracts with BARDA; market acceptance of our products and product candidates; our ability to maintain adequate protection of our intellectual property; competition risks; the need for additional financing; the impact of government laws and regulations and the impact of the COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the ability to recruit patients, the ability to conduct the studies in medical sites and the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts also may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products and product candidates in the future.

These and other significant factors are discussed in greater detail in MediWound's Annual Report on Form 20-F for the year ended December 31, 2020, filed with the Securities and Exchange Commission ("SEC") on February 25, 2021, Quarterly Reports on Form 6-K and other filings with the SEC from time-to-time. These forward-looking statements reflect MediWound's current views as of the date hereof and MediWound undertakes, and specifically disclaims, any obligation to update any of these forward-looking statements to reflect a change in their respective views or events or circumstances that occur after the date of this release except as required by law.

Contacts:
Boaz Gur-Lavie
Chief Financial Officer
MediWound Ltd.
ir@mediwound.com

Jeremy Feffer
Jeremy Feffer
Managing Director, LifeSci Advisors
212-915-2568
jeremy@lifesciadvisors.com

Source: MediWound Ltd.